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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/787,219	JESTIN ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 17-79* is/are pending in the application.

4a) Of the above claim(s) *9, 10, 23-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 17-22, 78, 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 6/4/2007 is acknowledged and has been entered. Claims 1-10, 17-20, 22, 78, 79 have been amended. Claims 11-16 have been cancelled. Claims 1-10 and 17-79 are pending. Claims 9-10 and 23-77 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-8, 17-22, 78-79 are discussed in this Office action. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejection

3. The objection to the specification is withdrawn in view of Applicant's amendment. The claim rejection under 35 USC 101 directed to claim 22 is withdrawn in view of Applicant's amendment. The claim rejection under 35 USC 112 first paragraph directed to claims 78 and 79 as failing to comply with the deposit requirement is maintained and discussed below. The claim rejection under 35 USC 112 second paragraph directed to claims 18 and 78 are withdrawn in view Applicant's amendment. The double patenting rejections are maintained and discussed below.

Claim Rejections - 35 USC § 112

4. Once again, claims 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification lacks deposit information for the inserts recited in claims 78 and 79. The specification at paragraphs 0150 through 0159 only recite that the inserts are deposited as CNCM in the Collection Nationale de Cultures de Microorganismes (CNCM) on February 27, 2004. The specification

provides no extensive information for one of skill in the art to produce cell recited therein. Therefore, the specification is not considered sufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met for the claimed deposit. If a deposit is made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicant(s), or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, than in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:
(a) During the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
(b) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) The deposit will be maintained in a public for the enforceable life of the patent;
(d) A test of the viability of the biological material at the time of the deposit (see 37 CFR 1.807); and
(e) The deposit will be replaced if it should ever become inviable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each Member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository along with a statement verifying whether or not the deposit was made under the Budapest Treaty is required to meet the requirements of a deposit.

Double Patenting

5. Once again, claims 1-8, 17-22 and 78 and 79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 14-18, 65 and 66 of copending Application No. 10/590810. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims 1-8, 17-22 and 78 and 79 of the instant invention and the claims 1-7, 14-18, 65 and 66 of copending application 10/590810 are drawn to a purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having at least 80% identity to nucleotide residues of SEQ ID NO: 26, and wherein the polypeptide has at least one mutation in A331, L332, D333, S335, Y334 and M484 and wherein said polypeptide has DNA polymerase activity. The claims are further drawn to a vector; host cell and DNA insert comprising the purified polynucleotide or polypeptide.

The claims 1-7, 14-18 and 65 and 66 of copending application '810 only differ from the instant invention in that they further recite wherein the polypeptide has a mutation in amino acids 13-555 of SEQ ID NO: 26. Thus, the claims 1-8, 17-22 and 78-79 of the instant invention falls entirely within the scope of the claims the claims 1-7, 14-18, 65 and 66 of copending application '810. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. Miller, 151, U.S. at 198; See Stanley, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., Titanium metal corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Omum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Once again, claims 1-8, 17-22 and 78 and 79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 14-18, 65 and 66 of copending Application No. 11/065,943. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims 1-8, 17-22 and 78 and 79 of the instant invention and the claims 1-7, 14-18, 65 and 66 of copending application 11/065943 are drawn to a purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having at least 80%

identity to nucleotide residues of SEQ ID NO: 26, and wherein the polypeptide has at least one mutation in A331, L332, D333, S335, Y334 and M484 and wherein said polypeptide has DNA polymerase activity. The claims are further drawn to a vector; host cell and DNA insert comprising the purified polynucleotide or polypeptide.

The claims 1-7, 14-18 and 65 and 66 of copending application '943 only differ from the instant invention in that they further recite wherein the polypeptide has a mutation in amino acids 13-555 of SEQ ID NO: 26. Thus, the claims 1-8, 17-22 and 78-79 of the instant invention falls entirely within the scope of the claims 1-7, 14-18, 65 and 66 of copending application '943. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"-- typically cannot support an independent valid patent. Miller, 151, U.S. at 198; See Stanley, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., Titanium metal corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Omum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

7. Applicant argues that the rejection under 35 USC 112 first paragraph for lack of deposit information should be withdrawn in view of the statement on access for biological deposit recited at page 20 of Applicant's remarks.

This argument is not found persuasive because Applicant did not amend the specification to recite access to the biological deposit materials as required by 37 CFR 1.808. To reiterate the rejection noted above, "amendment of the *specification to* recite the date of the deposit and the complete name and address of the depository along with a statement verifying whether or not the deposit was made under the Budapest Treaty is required to meet the requirements of a deposit." (See MPEP 2410.01). The rejections under 35 USC 112 first paragraphs as lacking deposit information is maintained.

8. Applicant argues that the provisional double patenting rejections should be held in abeyance pending the identification of otherwise allowable subject matter.

These arguments are not found persuasive, as the claims are not deemed in

condition for allowance. Additionally, it cannot be determined which of the applications would be published first if allowed. Therefore, the double patenting rejections are deemed necessary for the instant invention.

New Ground(s) of Rejection

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-8, 17-22 and 78-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "an amino acid sequence having at least 95% identity to SEQ ID NO: 26, wherein said polypeptide has a mutation at residue 484 of SEQ ID NO: 26 which replaces the methionine residue (Met) with a different amino acid residue" and "wherein said polypeptide has at least 97.5% identity to SEQ ID NO: 26" encompasses a large genus of nucleic acid species not adequately described or disclosed.

At page 4, Applicant teaches that the instant invention is directed to methods for identifying thermostable mutant polypeptides and their corresponding polynucleotide

sequence having catalytic activity. In the instant disclosure, Applicants discloses at page 22 that "a gene (polynucleotide) can also be used which encodes a corresponding or variant polymerase having at least 80% identity to SEQ ID NO: 26. Applicant states that theses "this gene (polynucleotide) can have various mutations. Applicant asserts that "for example, a mutation of one or more amino acids in amino acids 738 to 767 of SEQ ID NO:26. Applicant states that further examples of mutations include mutations at positions M470, F472, M484, and W550 A331, and S335. In a preferred embodiment, these mutations are A331T, S335N, M470K, M470R, F472Y, M484V, M484T, and W550R. Applicant disclosed at page 23, in a particularly preferred embodiment, the polynucleotides of the present invention encode polypeptides having one or more of the aforementioned mutations and share at least 85% identity, at least 90% identity, at least 95% identity, or at least 97.5% identity to the polypeptide of SEQ ID NO: 26. Applicant additionally states that moreover, polynucleotides of the present invention encode polypeptides that have DNA polymerase activity and/or 5'-3' exonuclease activity. In the examples and at page 23 and 35, the specification identifies that the Methionine at position 484 of SEQ ID NO: 26 is replaced with either a valine or threonine residue (M484V or M484T).

However, no other sequences, which having at least 80% homology or 95% homology or 97.5% homology to the sequence of SEQ ID NO: 26 and having a mutation at residue 484 wherein methionine is replace with any other different amino acid residue and exhibiting the similar function is disclosed. The specification does not disclose a correlation between the claimed function and the structure of the sequence such that

the skilled artisan would have known what other modifications, besides M484V or M484T, such that the skilled artisan would have known what modifications could be made of the very large number of modification potentially encompassed by the claims without the claims losing function. The specification does not provide sufficient guidance or information for one skilled in the art to predict what the undisclosed at least 95% or 97.5% homology region of SEQ ID NO: 26 are in the context of the claims. Thus the specification does not show that Applicant had possession of the full scope of the claimed invention at the time the application was filed.

Conclusion

11. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637

8/9/2007